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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BING LI, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AETERNA ZENTARIS, INC., DAVID A. DODD, JUERGEN ENGEL, DENNIS TURPIN, JUDE DINGES, RICHARD SACHSE, and PAUL BLAKE, Defendants,	Case No.: 3:14-CV-07081-PGS **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiffs Gregory Vizirgianakis, Phong Thomas Dinh, and Jamshid Khodavandi ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Aeterna Zentaris, Inc. ("Aeterna" or the "Company"), with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Aeterna; (c) review of other publicly available information concerning Aeterna; and (d) discussions with an FDA regulatory and drug development expert familiar with the relevant facts herein. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities that purchased or otherwise acquired Aeterna securities during the period from August 30, 2011 through November 6, 2014, both dates inclusive, and who did not sell such securities prior to November 6, 2014 (the "Class Period"), and were damaged thereby (the "Class"). Plaintiffs seek to pursue remedies under Sections 10(b) and

20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Aeterna is a biopharmaceutical company engaged in developing treatments in endocrinology and oncology. The Company's pipeline is comprised of compounds at various stages of development, none of which have been approved for commercial sale to the public and it had virtually no operating revenue during the Class Period.

3. One of Aeterna's primary drug development candidates was AEZS-130 (marketing name: Macrilen, and was also known as "Solorel" and "macimorelin"). AEZS-130 is a growth hormone stimulator intended to diagnose whether a person has adult growth hormone deficiency ("AGHD").

4. Aeterna acquired the rights to AEZS-130 from Ardana Bioscience Ltd. ("Ardana") in 2009 for $232,000. Ardana had partially completed a Phase 3 study of AEZS-130, but suspended the study when it ran into financial difficulties. Aeterna acquired from Ardana the rights to AEZS-130 along with this study, including all of the data generated in the study.

5. In an effort to gain FDA approval for commercialization of AEZS-130, Aeterna discussed extensively with the FDA how to complete the Phase 3 study. FDA and Aeterna agreed that Aeterna could complete the study and file a

New Drug Application ("NDA") with the FDA by, using the data generated in the Ardana portion of the study, and in addition, enrolling an additional 50 subjects.

6. To formalize this agreement, on December 20, 2010, Aeterna agreed to a Special Protocol Assessment ("SPA") with the FDA. The SPA is a binding agreement that governed the design, subject inclusion criteria, minimum number of subjects, clinical endpoints, and specific statistical analyses for Aeterna's Phase 3 study of AEZS-130. In other words, once Aeterna reached an agreement with the FDA on the SPA, Aeterna was formally bound to conduct the Phase 3 trial and analyze the data collected from it in accordance with the terms established by the SPA.

7. A successful Phase 3 study conducted in strict accordance with the terms of the SPA forms the primary basis for any claim by Aeterna that AEZS-130 has shown "efficacy" that will be part of any New Drug Application ("NDA"). Failure to conduct the study or the planned analysis in accordance with the terms of the SPA will cause the FDA to reject the NDA.

8. During the Class Period, defendants repeatedly touted that AEZS-130 successfully met the primary endpoint of the Phase 3 study *in accordance with the terms of the SPA*. Specifically, defendants issued numerous press releases and other statements indicating that AEZS-130's Phase 3 trial, conducted under the

SPA, showed that the drug was effective for evaluating AGHD in accordance with the protocol agreed to in the SPA.

9. Defendants' claims that the Phase 3 study, under the terms of the SPA, showed AEZS-130 to be effective for diagnosing AGHD was false.

10. In truth, Aeterna's Phase 3 trial, when analyzed pursuant to the terms of the SPA, actually ***failed*** to show that AEZS-130 was an effective diagnostic test for AGHD. In fact, AEZS-130 was only arguably "effective" when Aeterna manipulated the data and threw out the results from two patients from the Ardana portion of the Phase 3 study, in clear violation of the protocol Aeterna agreed to in the SPA.

11. When all of the study subjects were included in the planned analysis pursuant to the terms of the SPA, AEZS-130 failed to show efficacy. Yet, Aeterna consistently misrepresented to investors that the planned analysis called for by the SPA proved efficacy.

12. Aeterna's senior officers, including Blake and Pelliccione, attended a pre-NDA meeting with the FDA before submitting the NDA in November 2013, and were present when the FDA stated that it disagreed with Aeterna's decision to submit a primary statistical analysis for efficacy that excluded from the final dataset two AGHD patients that Aeterna believed were not confirmed cases.

13. The FDA disagreed with Aeterna because the primary statistical analysis agreed to in the SPA was to be performed on the entire patient dataset (i.e., all of the patients entered into the study), rather than a sub-group of Aeterna's own choosing. It is also improper to exclude subjects from the final dataset for primary analysis once the trial has concluded, the dataset locked, and the results analyzed. Aeterna's decision to exclude the two subjects was made only after Aeterna had completed the statistical analysis on the full patient dataset required by the SPA and learned that AEZS-130 had not proven effective.

14. Only after sifting through and manipulating the data in a desperate attempt to show efficacy did Aeterna claim that it was appropriate to exclude the two AGHD patients from the final dataset. By running alternative statistical analyses, Aeterna determined it could make a case that AEZS-130 was effective by excluding two confirmed AGHD patients who it claimed had not been correctly diagnosed as having AGHD after being given AEZS-130. The FDA, accustomed to such maneuvering, made clear that it did not accept Aeterna's after-the-fact exclusion of two patients from the primary patient analysis.

15. Notwithstanding having been told by the FDA that its plan to exclude the two AGHD subjects from the final dataset for primary analysis was unacceptable and a violation of the SPA, Aeterna submitted its NDA with a final

dataset and primary statistical analysis that excluded the two AGHD patients. Aeterna knew that its NDA was extremely unlikely to be approved, yet pressed ahead anyway because its primary goal was to raise millions of dollars from investors based on its false claims that AEZS-130 had proven effective in diagnosing AGHD.

16. In a series of public announcements from August 30, 2011 through March 21, 2014, Aeterna continually misrepresented that the AEZS-130 Phase 3 study had met its primary endpoint for efficacy and that AEZS-130 had proven effective according to the parameters of the SPA.

17. Based on the strength of the "successful" Phase 3 trials for AEZS-130 that appeared certain to lead to FDA approval and large profits, Aeterna sold nearly $75.0 million of its common stock to the investing public during the Class Period.

18. Subsequently on November 6, 2014, the U.S. Food and Drug Administration ("FDA") denied Aeterna's application to market the AEZS-130 publicly, because "the planned analysis of the Company's pivotal trial did not meet its stated primary efficacy objective as agreed to in the Special Protocol Assessment agreement letter between the Company and the FDA", which required that all of the patients diagnosed as having AGHD in the study be included in the

statistical analysis. Instead Aeterna excluded from its statistical analysis the results of two of the AGHD subjects enrolled in the study, in violation of the parameters of the SPA. When these two subjects were included in the analysis, AEZS-130 did not reach its primary endpoint and was not effective. Thus, FDA refused to approve AEZS-130.

19. On November 6, 2014, when Aeterna announced publicly that the FDA denied Aeterna's NDA for AEZS-130 because Aeterna's statistical analysis failed to abide by the SPA and excluded subjects that the protocol required be included, Aeterna's stock price plummeted on heavy volume to close at $0.65 per share, a decline of almost 50% from the previous day's closing of $1.29 per share. Aeterna's stock is now trading at $0.07 per share.

JURISDICTION AND VENUE

20. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78b-1 and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5.

21. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

22. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), because Aeterna's common stock traded on the NASDAQ stock exchange and at times relevant to this complaint, Aeterna maintained an office in this District.

23. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

24. Lead Plaintiff Gregory Vizirgianakis purchased Aeterna securities at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

25. Lead Plaintiff Phong Thomas Dinh purchased Aeterna shares at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

26. Lead Plaintiff Jamshid Khodavandi purchased Aeterna shares at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

27. Defendant Aeterna Zentaris, Inc. is a Canadian corporation with its principal place of business at 1405 Blvd. du Parc-Technologique, Quebec City, Quebec, Canada GIP 4P5, and at times relevant to this complaint up until the present date, maintained offices at 25 Mountainview Blvd., Suite 203, Basking Ridge, NJ 07920, through its wholly owned subsidiary Aeterna Zentaris, Inc., a Delaware corporation. During the Class Period, Aeterna's common stock was actively traded on NASDAQ, under the ticker "AEZS."

28. Defendant Juergen Engel ("Engel") was the Company's President and CEO from September 2008 to April 2013. Engel had personal knowledge of the statistical analysis that Aeterna submitted to the FDA and was aware that it violated the statistical analysis plan agreed to with the FDA in the SPA. Engel indicated to investors on numerous conference calls described below that he was attending the pre-NDA meeting with the FDA and would therefore have been present when the FDA stated that it disagreed with Aeterna's decision to exclude

the two AGHD patients that Aeterna believed were not confirmed cases.[1] Engel was quoted making false statements in the August 30, 2011 press release that AEZS-130 had proven effective according to the parameters of the SPA. He also signed each false and misleading Form 20-F during the Class Period until his departure in April 2013.

29. Defendant David A. Dodd ("Dodd") has served as the Company's President and CEO since April 2013. Prior to joining Aeterna as President and CEO, Dodd undertook a thorough review of Aeterna's pipeline of drugs under development. This includes reviewing the FDA file for AEZS-130, which would have quite clearly revealed FDA's position that it believed Aeterna's exclusion of two AHGD patients from the final dataset for primary analysis of AEZS-130 violated the terms of the SPA.

30. Defendant Paul Blake ("Blake") was the Company's Chief Medical Officer from August 5, 2007 until March 13, 2014. Blake is identified as one of the four senior corporate officers of Aeterna in its annual reports during the Class Period.[2] As Chief Medical Officer, Blake had intimate knowledge of the AEZS-130 clinical study results and the statistical analysis that Aeterna submitted to the

[1] Even if Engel had not personally attended the pre-NDA meeting, Engel was directly informed about the entire substance of the meeting by those who did attend, including Pelleccione and Blake.

[2] The other senior corporate officers were CEO Engel, CFO Turpin and Senior Vice President of Regulatory Affairs, Pelliccione.

FDA and was aware that it violated the statistical analysis plan agreed to with the FDA in the SPA. As Chief Medical Officer, Blake, along with Mr. Pelliccione, were the primary persons responsible for explaining to the FDA at the pre-NDA meeting and in other communications Aeterna's rationale for excluding the two AGHD patients from the final dataset for primary analysis. Based on his statements in investor conference calls, Blake personally attended the pre-NDA meeting with the FDA and was present when the FDA stated that it disagreed with Aeterna's decision to exclude the two AGHD patients that Aeterna believed were not confirmed cases.

31. Nicholas J. Pelliccione ("Pelliccione") served as Company's Senior Vice President, Regulatory Affairs and Quality Assurance from May 2007 through March 2014. Pelliccione is identified as one of the four senior corporate officers of Aeterna in its annual reports during the Class Period. Mr. Pelliccione, along with Mr. Blake, were primarily responsible for explaining to the FDA at the pre-NDA meeting and in other communications Aeterna's rationale for excluding the two AGHD patients from the final dataset. Based on his statements in investor conference calls, Pelliccione personally attended the pre-NDA meeting with the FDA and was present when the FDA stated that it disagreed with Aeterna's decision to exclude the two AGHD patients that Aeterna believed were not

confirmed cases. At Aeterna he had top-line responsibility for clinical and preclinical regulatory aspects of AEZS-130.

32. On numerous investor conference calls described below, Engel identified Blake and Pelliccione as the senior officers of Aeterna with responsibility for, and knowledge of, the details of Aeterna's discussions with FDA about the protocol requirements for the Phase 3 clinical study for AEZS-130, the required statistical analysis for the SPA and for an approvable NDA, and for all other clinical and regulatory issues related to AEZS-130. Blake and Pelliccione were involved in regular direct discussions with the FDA concerning the details of the AEZS-130 Phase 3 trial, including the planned statistical analysis under the SPA and also Aeterna's proposed alternative analysis not permitted under the SPA that excluded the two AGHD patients.

33. Defendants Dodd, Engel, Pelliccione, and Blake are collectively the "Individual Defendants."

ALLEGATIONS OF MISCONDUCT

Background

34. Aeterna is a biopharmaceutical company engaged in developing treatments in endocrinology and oncology. The Company's pipeline is comprised of compounds at various stages of development, none of which have been

approved for commercial sale to the public. During the Class Period it had no meaningful operating revenue, and had negative operating cash flow in excess of $20.0 million annually.

35. AEZS-130, until recently, was the Company's drug which was most advanced on the path to commercialization. AEZ-130 is an orally-administered drug designed primarily to evaluate and diagnose whether a person has AGHD.

36. The development of AEZS-130 was first initiated by Ardana Bioscience Ltd ("Ardana") in 2007. Due to financial problems at Ardana, Aeterna was able to acquire all rights to AEZS-130 from Ardana on June 8, 2009 for $232,000, including all of the clinical data and related assets comprising Ardana's incomplete Phase 3 clinical trial of AEZS-130.

37. In the process of purchasing the rights to AEZS-130 from Ardana, Aeterna performed a thorough due diligence investigation on AEZS-130, including carefully evaluating the data for the incomplete Phase 3 clinical trial that Ardana had initiated. Specifically, the data showing whether each subject enrolled in Ardana's study was properly classified and met the inclusion and exclusion criteria established in the SPA was available to, and carefully reviewed by, Aeterna.

38. Indeed, defendant Juergen Engel admitted on a November 13, 2008 conference call that "we're getting all the data back [from the Ardana study] and we are at present evaluating" its potential.

39. Defendant Dodd also admitted on a November 7, 2014 investor conference call that Aeterna evaluated the data obtained from Ardana's Phase 3 study ***before*** it decided to proceed with the Phase 3 study of AEZS-130 and ***before*** it entered into the SPA with the FDA.

40. On October 19, 2009, Aeterna announced that it would complete the Phase 3 study of AEZS-130, which Ardana had started, and that it was in discussion with the FDA regarding how to best complete the Phase 3 trial.

41. On a November 11, 2009 conference call, defendant Engel stated that Pelliccione was in direct communication with the FDA regarding the plan for completion of the Phase III study.[3]

42. Again on a March 24, 2010 conference call, asked for an update on discussions with the FDA on how to continue and complete the Phase III trial on AEZS-130, defendant Engel stated: "We are looking forward to a meeting with the FDA in the near future."

[3] Pelliccione stated on the 11/11/2009 call: "So we are working with the agency to develop an appropriate control to complete that study. And we have a proposal in with the agency, which they are currently reviewing, but we have not heard back from them yet. We expect to hear back from them in the near future. And once we hear from them we will have a way forward to complete the trial."

43. On the same March 24 call, Pelliccione added "Yes. … we have submitted a proposal to the agency. They're discussing it internally. We want to make sure we have all of the appropriate people on our side available for this discussion. So part of it is getting the proposal in front of the FDA, which we've done, and now the FDA is in the process of reviewing it and we're trying to arrange an actual meeting date. And if you're familiar with the FDA, they may propose one date, but if it's not acceptable for us because of other commitments, we have to go back and forth a couple of times until we can come up with a date that's mutually acceptable for all of us to be available. We expect to get that nailed down pretty quickly, and hope to have that meeting within the next, I don't know, month or 2 at the latest."

44. Then defendant Engel confirmed: "Yeah. So the reason why this meeting is so important, we want to involve their top opinion leaders and sometimes they have limited time. So we are at present discussing on an exact time for this face-to-face meeting and this will be done shortly."

45. On August 12, 2010, defendant Engel acknowledged that "Over the quarter and in recent weeks, we had positive discussions with the FDA on the best way of completing the current Phase 3 trial as a diagnostic test for growth hormone deficiency in adults,…". Pelliccione then made clear that: "We – we have been

discussing this with the agency as you've said for a while and we are – we have been in active discussions with the review division and have met with them and made a proposal to them on how we want to complete the Phase 3 trial. **This was a detailed discussion involving the clinical and statistical group and it basically revolved around how we can move forward to complete the trial**. We've made the submission to them and they are in the process of reviewing it, and we expect to hear back from them relatively soon. That's pretty much as far as I can go at this point, because until we actually hear back from them, we won't know whether or not our proposal has been accepted." (emphasis added). Because these discussions with the FDA concerned the "clinical and statistical group" for AEZ-130, Pelliccione, Blake and Engel were aware that the FDA required it to analyze data from the entire patient dataset, i.e. the intent-to-treat group, rather than a select sub-group of Aeterna's choosing.

46. On a November 9, 2010 conference call, Pelliccione stated that "We have been discussing this program with the FDA for quite a while. And as you're probably aware, sometimes discussions with the FDA can get rather protracted. There really has been no major obstacle in the discussion; it's been more a matter of getting them to give us a final response on how we have proposed to complete the trials. And we – what I can say now is that we believe we're in the absolute

final stages of this and should have an answer from them within a reasonably short period of time."

47. Finally in December 2010, the FDA definitively outlined for Aeterna what was required for it to complete the Phase 3 trial of AEZS-130. The requirements for the Phase 3 trial were memorialized in an agreement between FDA and Aeterna called a "Special Protocol Assessment" or SPA.

The Special Protocol Assessment

48. On December 20, 2010, Aeterna announced that it had agreed to the SPA with the FDA for the completion of the Phase 3 study for AEZS-130. This meant that AEZS-130's Phase 3 trial must be conducted, and its data analyzed, in accordance with the clinical protocol and statistical analysis plan set forth in the SPA. If the Phase 3 trial and its data analysis was conducted pursuant to the SPA and the results met the objectives outlined in the SPA, the FDA would then have accepted the efficacy of AEZS-130.

49. Pursuant to section 505(b)(4)(B) of the Federal Food, Drug and Cosmetic Act, a SPA is binding on both the sponsor (i.e. Aeterna) and the FDA, and may not be changed except by written agreement of both the sponsor and the FDA. If the sponsor deviates from the parameters of the SPA without obtaining

approval from the FDA, the FDA will interpret that as the sponsor's understanding that the agreement is now void.

50. FDA Guidance specifically states: "the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident."[4] Thus, not conducting the clinical trial according to the SPA will result in the rejection of the NDA.

51. A critical part of the SPA is the "statistical analysis plan" ("SAP"), which governs the planned statistical analysis of a clinical study. The SAP defines all the statistical output from the study which will be included in the clinical results, and includes specific procedures for the statistical analyses of the primary and secondary endpoints and other data.

The Phase 3 Study

52. The Phase 3 study for AEZS-130 consisted of two parts: the first part of the study was conducted by Ardana, and the second part by Aeterna.

53. According to Aeterna's December 20, 2010 press release (attached hereto as Exhibit 1), the part of the study completed by Ardana included: "42 patients with confirmed AGHD or multiple pituitary hormone deficiencies and a

[4] FDA Guidance for Industry, Special Protocol Assessment, Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), May 2002.

low insulin-like growth factor-I" and "[a] control group of 10 subjects without AGHD were matched to patients for age, gender, body mass index and (for females) estrogen status." (emphasis added).

54. The effectiveness of AEZS-130 was then to be compared to a drug that was already on the market, known as GHRH.

55. In 2008, however, GHRH was removed from the market, and therefore when Aeterna took over the Phase 3 study of AEZS-130, the comparator drug was no longer in existence.

56. Aeterna and the FDA reached agreement on a SPA, which called for, among other revisions, the following changes to Ardana's existing study in light of GHRH being pulled from the market:

- An additional 30 normal controls subjects to be enrolled to match the AGHD patients from the original cohort;
- An additional 20 subjects be enrolled - 10 AGHD patients and 10 matched normal control subjects;
- The entire database would therefore include approximately 100 patients (52 from the earlier Ardana study and 50 from Aeterna's part of the study).

57. On a March 22, 2011 conference call Engel reiterated that Aeterna had entered into the SPA in December 2010 and enumerated the specific steps required for Aeterna to complete the Phase 3 study for AEZS-130, including the number of patients required to be enrolled and analyzed under the terms of the SPA. Asked on the call whether "the FDA had responded positively to your meetings with them and you knew exactly what you needed to complete this Phase III trial," defendant Blake responded: "Yes, ***the FDA did give us an answer, and it was very clear***, but it was very slow, Ren. So it truly was right at the end of the year when we got it. We've implemented the requirements and recommendations from them, and we will finish the study in the second quarter or just by or before the end of the first half of this year." Aeterna, therefore, was in constant communication with the FDA and knew exactly what the FDA's position was concerning the requirements for successful completion of the Phase 3 study.

58. On May 18, 2011, defendant Engel stated: "For AEZS-130, we will complete the Phase III study under SPA in the U.S. as a diagnostic test for Adult Growth Hormone Deficiency, and in case of positive results will file an NDA for this indication in the U.S."

59. On the May 18 call, an analyst asked whether Aeterna will release to investors the results of the AEZS Phase 3 study, Defendant Blake responded: "Yes,

we will be announcing the results when we've completed the trial and have the analyses made and all the checks done so that the data will be solid and secure. And we expect that information sometime in the third quarter." (emphasis added)

60. In a July 26, 2011 press release (attached hereto as Exhibit 2), Aeterna announced completion of the Phase 3 Study of AEZS-130 and stated it "is currently proceeding with detailed analyses of the data and preparing for a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in the upcoming months." The press release detailed: "The first part of the study conducted by Ardana was a two-way crossover study involving 42 patients with confirmed AGHD or multiple pituitary hormone deficiencies and a low insulin-like growth factor-I."

61. On an August 10, 2011 conference call, Engel stated: "Preliminary results are very encouraging and therefore we're currently proceeding with detailed analysis of the data and preparing for a pre-NDA meeting with the FDA in the upcoming months, which would be followed by the filing of an NDA for the registration of AEZS-130 … ."

62. On the August 10 call an analyst asked Blake "And unless I missed it, we haven't seen the data for this completed trial. Is that correct? And might we be

seeing it at a presentation?" Blake responded: "I think ***we've got all the data in-house. It's a very technical laboratory-based answer with an awful lot of statistics***. And I have to confess I don't fully understand not being a statistician. ***But the protocol is very clear, was agreed with the FDA. We are going through the final data assessments.*** We expect to release those top line results and hopefully the world will be able to understand them shortly."

63. Thus, Aeterna knew that its alternative statistical analysis that excluded two AGHD patients violated the planned analysis agreed to with the FDA in the SPA.

Aeterna Misleadingly Touts "Successful" Phase 3 Study

64. On August 30, 2011, Aeterna issued a press release announcing "favorable top-line results" of its "completed Phase 3 study" of AEZS-130. Aeterna also stated in the press release that "***[t]he parameters of the study...were achieved as agreed to with FDA under our Special Protocol Assessment (SPA). Importantly, the primary efficacy parameters show that the study achieved both specificity and sensitivity at a level of 90% or greater.***" (emphasis added).

65. The August 30, 2011 press release was false and misleading because AEZS-130 was not shown effective in the Phase 3 study according to the terms or parameters of the SPA. Aeterna concealed that if all 52 confirmed AGHD patients

had been included in the primary analysis as required by the SPA, FDA guidance, and standard industry practice, then AEZS-130 would not have reached its primary efficacy end-point and would not have demonstrated efficacy.

66. Aeterna's claim that AEZS-130 was effective was misleading because instead of disclosing the results of the statistical analysis on the entire patient dataset in the intent-to-treat group which was the primary analysis required by the SPA, FDA guidance and standard industry practice, Aeterna disclosed its analysis of a sub-group that it considered "more appropriate" for determining the efficacy of AEZS-130. In fact, Aeterna misled investors to believe the positive results were from the planned statistical analysis required by the SPA, stating in part: "The first part of the study conducted by Ardana was a two way crossover study involving 42 patients with confirmed AGHD … .". In fact, the positive efficacy results were from a statistical analysis that improperly excluded two AGHD patients.

67. Aeterna's August 30, 2011 press release (attached hereto as Exhibit 3) also stated that Aeterna was "preparing for a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in the upcoming months, which would be followed by the filing of a NDA for the registration of AEZS-130 in the United States."

68. That same day Bloomberg LLP reported: "Aeterna Zentaris rose to highest since July 27 intraday in U.S. trading after Phase 3 results showed AEZS-130 reached primary endpoint demonstrating >90% area-under-the-curve of Receiver Operating Characteristic curve. Aeterna sees meeting with U.S. FDA in coming months to prep for NDA of AEZS-130 as first oral test for diagnosis of Adult Growth Hormone Deficiency. AEZS up 10% after climbing as much as 14%."

69. In a November 10, 2011 conference call with investors, defendant Engel misrepresented: "Now for AEZS-130, our novel orally active ghrelin agonist. Last July, we completed our Phase 3 trial with AEZS-130 as an oral diagnostic test for adult growth hormone deficiency and in August we presented favorable topline results for this study. Results showed that AEZS-130 reached its primary end point by demonstrating more than 90% area-under-the-curve of the Receiver Operating Characteristic curve, which determines the level of specificity and sensitivity of the product."

70. Also on the November 10 conference call, Engel stated "We recently received confirmation of a pre-NDA meeting with the FDA before year-end, which we expect, depending on the outcome of this meeting, to be followed by the filing

of an NDA for the registration of AEZS-130 in the United States in the first half of 2012."

71. On the November 10 conference call, an analyst asked Engel "And then on AEZS-130, could you just give us an idea what you're looking to get out of this pre-NDA meeting, is it anything more than just confirmation of discussions you've had in the past with the FDA? What you expect to submit to the FDA in the NDA? And then what are the gating factors after that meeting to actually submission?" Engel referred the question to Pelliccione who responded: "that's precisely what we were looking to obtain from the meeting. ***We have provided to them our strategy for what we will include in the submission, provided some preliminary clinical data that we will discuss that. And then get their agreement on the various parts of the NDA that we plan to submit***. And then from there we will move towards submitting the NDA in the first half of next year." This evidences that Pelliccione and other senior officers at Aeterna discussed the clinical data and results with FDA, whether Aeterna's proposed alternative primary analysis that violated the SPA would be acceptable to the FDA.

72. In Aeterna's year 2011 Form 20-F, filed with the SEC on March 28, 2012, the Company stated:

- Our lead program in endocrinology, a Phase 3 trial ***under a Special Protocol Assessment ("SPA")*** obtained from the FDA with AEZS-

130 as an oral diagnostic test for adult growth hormone deficiency ("AGHD"), ***has been completed with positive results***.

- On August 30, 2011: We reported favorable top-line results for the completed Phase 3 study for AEZS-130 as a first oral diagnostic test for AGHD. We also announced our intention to meet with the FDA for the future filing of a New Drug Application ("NDA"). The results showed that AEZS-130 reached its primary endpoint demonstrating >90% area-under-the-curve ("AUC") of the Receiver Operating Characteristic ("ROC") curve, which determines the level of specificity and sensitivity of the product.
- ***The parameters of the study were achieved as agreed to with the FDA under our SPA.*** Importantly, the primary efficacy parameters showed that the study achieved both specificity and sensitivity at a level of 90% or greater.

(emphasis added).

73. The 2011 Form 20-F misled investors to believe these positive results were from a statistical analysis of all of the patients in the intent to treat group as required by the SPA: "The first part of the study conducted by our former partner, Ardana, was a two-way cross-over study and ***included 42 patients with confirmed AGHD*** … ." (emphasis added) There was no suggestion that the positive efficacy results were only achieved by excluding two AGHD patients in violation of the SPA. And that the proper primary statistical analysis required by the SPA showed that AEZS-130 was not effective.

74. On March 28, 2012, in a conference call with investors, Engel stated:

> Now, for AEZS-130, our novel orally active ghrelin agonist. Last July, we completed our Phase 3 trial with AEZS-130 as an oral diagnostic test for adult growth hormone deficiency and in August we reported several top-line results for this study. Results showed that AEZS-130 reached its primary endpoint by demonstrating greater 90% area under the curve of the receiver operating characteristic, which determines the level of specificity and sensitivity of the product.

75. Engel also stated "We are in active discussion with the FDA and expect to meet with them in the first half of this year. The goal of the meeting will be to establish the overall content and format of our NDA for AEZS-130."

76. On the March 28 call, an analyst asked about "next steps towards regulatory submission [for AEZS-130] and perhaps comment on the level of interaction you're having with FDA? Pelliccione responded:

> We've been in active discussions with the FDA recently and are moving towards a pre-NDA meeting with them. ***We've been discussing our final clinical results and the format of our clinical study report*** as well as the other aspects of the NDA particularly our CMC section. We have provided a request to them and based on normal FDA procedure they are in the process of reviewing our meeting request and will get back to us on when a meeting date will be. We expect that to be in the first half of this year. (emphasis added)

77. On May 9, 2012 on an investor conference call defendant Engel stated:

> Now for AEZS-130 our novel oral active ghrelin agonist as a diagnostic test for growth hormone deficiency in adults. During the quarter, we continued discussions with the FDA in preparation for a meeting at the end of this month regarding our NDA submission. The

> goal of the meeting will be to establish the overall content and format of our NDA, which we expect to file by the end of the year.

78. On the May 9, an investor then asked "And when we go to the AEZS-130, again, what's the timing there for the NDA?" Engel responded "We will have a meeting with the FDA at the end of this month. And from there, we will exactly know what will be the timing. We still anticipate at this time to have the filing possible by the end of this year."

79. Thus, Engel was directly involved in discussions with FDA concerning Aeterna's NDA submission for AEZS-130.

80. In or around late May, 2012, Aeterna finally held the pre-NDA meeting with the FDA. Senior Aeterna officials, including Blake and Pelliccione, attended this meeting.

81. According to FDA regulation 21 CFR 312.47(b)(2), "The primary purpose of this kind of [the pre-NDA meeting] is to uncover any major unresolved problems, to identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness, …, to acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information), [and] to discuss appropriate methods for statistical analysis of the data … . The issue of excluding enrolled and verified

patients from the final data analysis, therefore, was discussed at this pre-NDA meeting.

82. During the pre-NDA meeting, Aeterna informed the FDA that it intended to rely for confirmation of efficacy on an alternative statistical analysis that excluded data from two patients who did not have confirmed AGHD. This was not the primary analysis called for in the SPA or clinical trial protocol. The FDA disagreed with Aeterna that it was appropriate to exclude these two patients from the primary analysis for confirmation of efficacy. Defendant Dodd later admitted on a November 7, 2014 conference call that: "[The FDA] believe that if you have been inappropriately classified, then those data still belong in that group where they shouldn't have been classified...***and so we've had a lot of discussions with them*** … [.]"

83. Despite having been informed by the FDA at the pre-NDA meeting and in numerous discussions following the pre-NDA meeting that it was inappropriate to exclude two patients the primary statistical analysis, Aeterna nevertheless went ahead and filed the NDA for AEZS-130, knowing that the FDA disagreed with the robustness of Aeterna's data and its analyses, that it violated the SPA and that the NDA would almost certainly be denied.

84. On June 26, 2012, Aeterna issued a press release (attached hereto as Exhibit 4) reiterating the final results of the Phase 3 drug trial with respect to AEZS-130. The press release stated in relevant part:

> Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZ) (the "Company") today announced that final Phase 3 results for its oral ghrelin agonist, AEZS-130, show that ***the drug is safe and effective in diagnosing adult growth hormone deficiency (AGHD)***.

85. Later that day, June 26, 2012, Bloomberg LLP reported "Aeterna Zentaris up as much as 42%, most intraday since June 2009, after phase 3 data shows AEZS-130 is safe/effective in diagnosing adult growth hormone deficiency."

86. Aeterna's Form 20-F for the year 2012, filed with the SEC on March 22, 2013, stated in relevant part:

- On August 30, 2011, we announced favorable top-line results of our completed Phase 3 study with AEZS-130 as a first oral diagnostic test for AGHD. The results showed that AEZS-130 had reached its primary endpoint demonstrating >90% area-under-the-curve ("AUC") of the Receiver Operating Characteristic ("ROC") curve, which determines the level of specificity and sensitivity of the product. ***Importantly, the primary efficacy parameters show that the study achieved both specificity and sensitivity at a level of 90% or greater.***

- On June 26, 2012, we announced that the final results from a multicenter, open-label Phase 3 trial for AEZS-130 showed that the drug is ***safe and effective*** in diagnosing AGHD.

- On October 18, 2012, we announced that results from a multicenter open-label Phase 3 trial for AEZS-130 demonstrated that the drug is ***safe and effective*** in diagnosing AGHD.

87. The statements in Aeterna's year 2012 Form 20-F described above were repeated in Aeterna's year 2013 Form 20-F, filed with the SEC on March 21, 2014.

88. The 2012 Form 20-F misled investors to believe these positive results were from a statistical analysis in accordance with the SPA. There was no suggestion that the positive efficacy results were only achieved by excluding two AGHD patients in violation of the SPA. And that the proper primary statistical analysis required by the SPA showed that AEZS-130 was not effective.

89. On May 8, 2013, on an investor conference call, Aeterna's new CEO David Dodd, who had replaced Engel as CEO, stated: "we're focused on completing the necessary elements of an NDA submission – for submission, pardon me. And this includes, we've completed discussions with the FDA to finalize our submission receiving good guidance from them. Based on this, we believe we are addressing the various elements advised in their correspondence." Dodd stated that Pelliccione was in direct contact with FDA concerning submission of Aeterna's NDA for AEZS-130. Pelliccione stated "Basically we've been talking to them on a pre-NDA basis, just to iron out some details about the –

completing the package … .” Blake added “We are targeted in working to file the NDA, submit the NDA in Q2.”

90. On November 6, 2013 in an investor conference call, Dodd disclosed that Aeterna had finally submitted to its NDA for AEZS-130 to the FDA the previous Monday, November 4, 2013.

91. On May 9, 2014 on an investor conference call, Dodd stated that the FDA had completed its mid-cycle review process for the AEZS-130 NDA. Dodd assured investors that Aeterna had had a “very good discussion with the entire FDA team, positive. We answered the questions, They asked the questions, we answered them, so we felt real good about it. …. But to-date, we've had continued interaction with the FDA. We've answered their questions. They continue to do their job and ask the different elements and we answer the questions. It's going well, I think, is the way I would look at.”

92. Again, on an August 8, 2014 conference call, Dodd stated “As for Macrilen, we continue our active discussions with and provide further information to the FDA, which is currently reviewing our NDA with a PDUFA date[5] of November 5.”

[5] A PDUFA date is when the FDA provides the sponsor with a decision on whether the NDA is approvable.

93. Each of the statements set forth above in Aeterna's press releases, and in each of its conference calls set forth above, and in each of its Form 20-Fs for fiscal years 2011-2013 (filed March 28, 2012, March 22, 2013 and March 21, 2014), were materially false and misleading for the following reasons:

(i) AEZS-130 was not shown effective in the Phase 3 study according to the terms or parameters of the SPA;

(ii) Aeterna concealed that if all 52 confirmed AGHD patients had been included in the primary analysis as required by the SPA, FDA guidance, and standard industry practice, then AEZS-130 would not have reached its primary efficacy end-point and would not have demonstrated efficacy;

(iii) Aeterna concealed that its positive AEZS-130 study results and claims of effectiveness resulted only from its throwing out the results of two AGHD patients in violation of the SPA and rerunning the statistical analysis on an incomplete and biased dataset;

(iv) Aeterna omitted to disclose that the NDA it had filed with FDA violated the SPA and improperly excluded two AGHD patients from the final dataset used for the statistical analysis that it was relying on to support its claims that AEZS-130 was effective;

(v) Aeterna omitted to disclose that in its pre-NDA discussions with FDA, FDA made clear that it would not accept as confirmatory Aeterna's proposed alternative statistical analysis of the Phase 3 study which did not conform to the SPA because it excluded two previously confirmed AGHD patients, and that approval of AEZS-130 must be based on the primary statistical analysis of all 52 previously confirmed AGHD patients in the intent to treat dataset as required by the SPA;

(vi) As a result of Aeterna's improper exclusion of two AGHD patients from the (primary) statistical analysis in violation of the SPA, it was almost certain that FDA would not approve Aeterna's NDA for AEZS-130.

94. On November 5, 2013, Aeterna submitted a New Drug Application for AEZS-130 with the FDA.

THE TRUTH EMERGES

95. On November 6, 2014, Aeterna announced that the FDA declined to approve the NDA for AEZS-130, because the Phase 3 trial did not actually meet the objectives outlined in the SPA. The press release states in relevant part:

> Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company") today announced that the Company has received a

> Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") for its New Drug Application ("NDA") for Macrilen ™ (macimorelin), a novel orally-active ghrelin agonist, for use in evaluating adult growth hormone deficiency ("AGHD"). ***Based on its review, the FDA has determined that the NDA cannot be approved in its present form.***
>
> The CRL mentions that ***the planned analysis of the Company's pivotal trial did not meet its stated primary efficacy objective as agreed to in the Special Protocol Assessment agreement letter between the Company and the FDA.*** The CRL further mentioned issues related to the lack of complete and verifiable source data for determining whether patients were accurately diagnosed with AGHD. The FDA concluded that, "in light of the failed primary analysis and data deficiencies noted, the clinical trial does not by itself support the indication." ***To address the deficiencies identified above, the CRL states that the Company will need to demonstrate the efficacy of macimorelin as a diagnostic test for growth hormone deficiency in a new, confirmatory clinical study.*** (emphasis added).

96. Aeterna issued this press release at 7 am on November 6, 2014, before the market opened. This adverse news that AEZS-130 had not proven effective in accordance with the planned analysis agreed to in the SPA, contrary to Aeterna's Class Period statements, caused Aeterna's stock to open at $0.63 per share, a decline of more than 50% from the previous day's closing price of $1.29 per share.

97. On November 7, 2014, Aeterna held a conference call with securities analysts to discuss the FDA's decision to deny approval of AEZS-130.

98. Dodd stated that the basis for the FDA's decision to deny approval was that: "In general, there is a difference with our view on the most appropriate

population for primary analysis of this study." Aeterna had based its case for AEZS-130's efficacy on analysis of a "per protocol" patient dataset[6] that excluded two AGHD patients who had previously been confirmed to have AGHD, but who Aeterna, after performing statistical analyses on the full intent to treat dataset, asserted had been misclassified and actually did not have AGHD. But Aeterna knew all along that the FDA required Aeterna to include all 52 AGHD patients in the primary analysis, as this was specified in the SPA and discussed with the FDA both before, at and after the pre-NDA meeting.

99. Dodd stated that the FDA was not satisfied with the "robustness" of Aeterna's per protocol analysis because Aeterna could provide no reliable evidence in the source data that the exclusion of the two confirmed AGHD patients was warranted.

100. The FDA insisted that confirmation of AEZS-130's efficacy be based on the entire dataset of patients that was planned for the primary analysis

[6] A per protocol analysis is based on a 'per protocol' set of subjects, sometimes described as the 'valid cases', the 'efficacy' sample or the 'evaluable subjects' sample, defines a subset of the subjects in the full analysis set who are more compliant with the protocol and is characterized by criteria such as the following: (i) the completion of a certain pre-specified minimal exposure to the treatment regimen; (ii) the availability of measurements of the primary variable(s); (iii) the absence of any major protocol violations including the violation of entry criteria. "The precise reasons for excluding subjects from the per protocol set should be fully defined and documented before breaking the blind in a manner appropriate to the circumstances of the specific trial." FDA Guidance ICH E9

pursuant to the SPA. Because Aeterna's proposed analysis excluded two previously confirmed AGHD patients, the FDA rejected it.

101. Defendant Dodd revealed on the conference call that AEZS-130 only met the SPA's objectives when data from the Phase 3 study is manipulated in violation of the SPA. Specifically, AEZS-130 was only shown effective when results from two previously-confirmed AGHD patients who Aeterna later asserted did not really have confirmed AGHD were excluded from analysis, and "when the patients who did not have confirmed AGHD were included, [AEZS-130] did not meet its primary endpoint."

102. Indeed, Aeterna could only achieve the SPA objectives for AEZS-130 when data from two patients were thrown out – in violation of the protocol and statistical analysis plan agreed to in the SPA.

103. With the benefit of Defendant Dodd's statements on the November 7, 2014 conference call, it becomes apparent exactly what improper manipulations Aeterna undertook to falsely manufacturer its claims of efficacy for AEZS-130. Aeterna's Form 20-F for the year 2011 states: "***Of the 53 AGHD subjects enrolled, 52 received AEZS-130, and 50 who had confirmed AGHD prior to study entry were included in this analysis, along with 48 controls.***" This statement indicates that only 50 of the 52 AGHD subjects that received AEZS-130 were included in

the final primary statistical analysis that Aeterna relied on to show efficacy submitted to the FDA.[7] Only with the benefit of Dodd's statements on the November 7, 2014 conference call is this discernible to investors. Prior to November 7, 2014, Aeterna concealed from investors that the results of the primary statistical analysis required by the SPA did not meet the primary end-point and did not show AEZS-130 to be effective.

104. Dodd's statements on the conference call make clear that the FDA believed that Aeterna's exclusion of these two AGHD subjects from the final data analysis was a clear violation of the clinical study protocols and the statistical analysis plan agreed to in the SPA. The FDA would have made its position clear to Aeterna in the pre-NDA meeting – before Aeterna submitted its NDA – because that is one of the central purposes of the pre-NDA meeting, discussing the proposed statistical analysis. Thus, Aeterna had no reason to expect that the FDA would approve the NDA.

105. Because the SPA included clear rules about which subjects should and should not be included in the primary data analysis, Aeterna knowingly and intentionally violated the SPA's statistical analysis plan when it decided, without obtaining approval from the FDA, to exclude the results of two patients from the

[7] A published paper describing the AEZS-130 Phase 3 study indicates that of the 53 AGHD subjects enrolled in the study, one dropped out prior to receiving AEZS-130 due to collapsed veins.

data analysis of AEZS-130's Phase 3 study. Aeterna only decided to exclude two AGHD subjects after it first ran the statistical analysis plan according to the SPA. When the study failed to meet the primary endpoints for efficacy under the required analysis, Aeterna decided to exclude these two patient's results and run a new analysis using the pretext that these two patients should not have been included in the Phase 3 study at all.

106. Dodd's excuse for throwing out results was that "not all patients classified as AGHD and enrolled in this during the initial phase of the study conducted by Ardana in fact met the protocol specified disease definition." Therefore, "such patients were excluded from analysis resulting in a dataset that we consider to be most appropriate for determination of the diagnostic utility of [AEZS-130]."

107. Dodd's explanation that Ardana misclassified two patients as having AGHD and that it was not until completion of the Phase 3 study and after the statistical analysis was complete that Aeterna learned of the misclassification is a false exculpatory statement. On four separate occasions, there was verification that all patients enrolled in the Phase 3 trial met the inclusion and exclusion criteria and were properly classified:

- Shortly after each newly enrolled subject entered the Phase 3 clinical trial, a clinical trial monitor visited each trial site and carefully reviewed the eligibility of each newly enrolled subject to ensure each subject was properly classified and met the inclusion and exclusion criteria. This is the specific task of a clinical trial monitor during their first visit to a clinical site after a new subject is enrolled in a clinical trial. FDA Guidance, ICH E6 states that "The monitor(s), in accordance with the sponsor's requirements, should ensure that the trial is conducted and documented properly by: … [v]erifying that the investigator is enrolling only eligible subjects.";[8]

- During Aeterna's due diligence process prior to acquiring the rights to AEZS-130 from Ardana and taking over responsibilities for the Investigational New Drug (IND) program from Ardana, Aeterna evaluated carefully the Phase 3 data for each AGHD subject. Defendant Engel admitted on a November 13, 2008 conference call that "we're getting all the data back [from the Ardana study] and we are at present evaluating" its

[8] FDA Guidance, ICH E6 also states that the monitor under Aeterna's direction should verify "that source data/documents and other trial records are accurate, complete, kept up-to-date, and maintained. " Thus, it was Aeterna's responsibility to make sure that there were "complete and verifiable source data for determining whether patients were accurately diagnosed with AGHD."

potential. Dodd also admitted on the November 7, 2014 conference call that Aeterna carefully evaluated the patient data before taking over the study;[9]

- During the process of negotiating the SPA with the FDA, Aeterna and the FDA did a thorough review of the enrolled patient data in order to determine the correct protocol and statistical analysis plan, including the appropriate patient group for the primary analysis for the completion of the Phase 3 trial. Aeterna's Chief Medical and Scientific Officer, Richard Sachse admitted on the November 7, 2014 conference call that the documentation surrounding the negotiation of the SPA with the FDA shows that neither Aeterna, nor the FDA raised the possibility that any of the 42 AGHD patients in the Ardana portion of the study might not have AGHD or might not be properly classified and included in the study as AGHD patients; and

- During Aeterna's quality control process just before data lock (i.e. the point at the conclusion of a clinical trial when no new patient data can be added or changed prior to undergoing the requested statistical analysis to support an NDA), it carefully reviewed the patient data.

[9] Dodd stated "Based on our evaluation of the data obtained from Ardana, we decided to proceed with the Phase 3 trial.".

108. As the sponsor of the study, Aeterna was responsible for monitoring the clinical trial to make sure that each patient met the required inclusion/exclusion entry criteria.[10] It was Aeterna's responsibility to review the data from the Ardana portion of the study and ensure that each patient met the study's eligibility criteria and was properly classified. And Blake, Engel and Dodd assured investors that Aeterna had carefully reviewed the data from the Ardana portion of the study in designing and agreeing to the terms of the SPA.

109. And Dodd admitted on the November 7, 2014 conference call that the FDA did not believe the source data for the Phase 3 trial supported Aeterna's position that the two previously confirmed AGHD patients were improperly classified as having AGHD.[11]

110. Dodd's excuse is also meaningless. Because the SPA is a binding agreement that cannot be unilaterally changed, Aeterna needed to seek permission from the FDA and mutually agree to modify the SPA before throwing out two subjects' results from its Phase 3 study.

111. The "Intent-to-Treat" principle states in conducting a clinical study, all randomized patients should be included in the (primary) analysis, in their

[10] See FDA Guidance, ICH E6.

[11] "The CRL further mentioned issues related to the lack of complete and verifiable source data for determining whether patients were accurately diagnosed with AGHD. The FDA concluded that, 'in light of the failed primary analysis and data deficiencies noted, the clinical trial does not by itself support the indication'."

assigned treatment groups. This avoids bias resulting from excluding certain patients who don't respond to treatment.

112. Pursuant to the SPA and the Intent-to-Treat principle, each of the 42 confirmed AGHD patients and ten controls from the Ardana portion of the study, and each of the 50 new patients from Aeterna portion of the study were required to be included in the primary statistical analysis for the AEZS-130 Phase 3 study.

113. FDA guidance "Statistical Principles for Clinical Trials – E9 states: "The intention-to-treat (see Glossary) principle implies that the primary analysis should include all randomised subjects.[12] Compliance with this principle would necessitate complete follow-up of all randomised subjects for study outcomes."

114. When designing a clinical trial the principal features of the eventual statistical analysis of the data should be described in the statistical section of the protocol. This section should include all the principal features of the proposed confirmatory analysis of the primary variable(s). … Only results from analyses envisaged in the protocol (including amendments) can be regarded as confirmatory." FDA Guidance, ICH, E9.

[12] International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use, ICH Harmonised Tripartite Guideline, Statistical Principles For Clinical Trials E9, Current Step 4 version, dated 5 February 1998.

115. "The set of subjects whose data are to be included in the main analyses should be defined in the statistical section of the protocol." FDA Guidance, ICH, E9.

116. Other relevant FDA guidance states:

> The validity of a clinical study would also be compromised by the exclusion of data collected during the study. There is long-standing concern with the removal of data, particularly when removal is non-random, a situation called "informative censoring." FDA has long advised "intent-to-treat" analyses (analyzing data related to all subjects the investigator intended to treat), and a variety of approaches for interpretation and imputation of missing data have been developed to maintain study validity. Complete removal of data, possibly in a non-random or informative way, raises great concerns about the validity of the study.

117. Here, only after the study was completed and the final dataset analyzed - and Aeterna learned that when all subjects in the intent to treat group are analyzed AEZS-130 does not meet its primary endpoint - did Aeterna change its prior determination and decide that two patients who previously it confirmed had AGHD, did not. This introduced bias into the study because Aeterna's decision to exclude the two patients was made with the knowledge that excluding them would turn the failed Phase 3 study into a successful one and change AEZS-130 from a failed drug into an approvable one.

118. Aeterna's excluding from the primary statistical analysis the results for two previously confirmed AGHD patients was in clear violation of the SPA and

its statistical analysis plan. Aeterna's numerous statements during the Class Period that the Phase 3 trial for AEZS-130 was conducted in accordance with the parameters of the SPA and proved effective according to the statistical analysis plan set forth in the SPA were therefore false and misleading.

119. AEZS-130 was only "effective" if Aeterna cheated - by throwing out data that did not conform to the results it wanted.

ADDITIONAL MOTIVE ALLEGATIONS

120. Aeterna filed the NDA for AEZS-130 despite knowing that it would almost certainly be denied because Aeterna was desperate for funds to stay afloat and wanted to raise money to fund the developmental stages of its various drugs under development. By announcing positive results for the AEZS-130 Phase 3 trial, Aeterna made investors believe that the FDA would approve an NDA for AEZS-130 and Aeterna would thereby earn substantial profits and the value of its stock would rise accordingly. It didn't matter if the FDA ultimately rejected the NDA for AEZS, so long as Aeterna was able to continue to sell stock and fund operations. Therefore, Defendants made misrepresentations about AEZS-130 to enable the Company to conduct numerous rounds of financing with investors,

raising more than $70 million from 2012 to 2014.[13] Offerings during the Class Period included, but were not limited to, the following::

(a) October 12, 2012: The Company announced the completion of a public offering of 6.6 million units consisting of one share of common stock and 0.45 of a 5 year warrant to purchase one common share at $3.45 per share. The offering generated net proceeds of approximately $15.2 million for the Company.

(b) May 21, 2013: The Company announced its entry into an "At-Market Issuance" agreement with MLV & Co. LLC for the Company, in its discretion, to sell a maximum of 2.5 million shares of common stock, up to an aggregate value of $4.6 million.

(c) July, 30, 2013: The Company announced the completion of a direct offering to certain institutional investors which garnered net proceeds of approximately $7 million.

(d) November 25, 2013: The Company announced the completion of a public offering of 13.1 million units consisting of one share of common stock and one whole 5 year warrant to purchase one common share at $1.60 per share. The offering generated net proceeds of approximately $13.7 million for the Company.

[13] Source: Aeterna's Form 20-F for the year 2014.

(e) January 14, 2014: The Company announced the completion of a public offering of 11 million units consisting of one share of common stock and 0.8 of a 5 year warrant to purchase one common share at $1.25 per share. The offering generated net proceeds of approximately $12.2 million for the Company.

(f) March 28, 2014: The Company announced that the SEC had declared Aeterna's shelf registration filed on Form F-3 effective, allowing the Company to sell up to $50 million in common shares in one or more "at-the-market" offerings during a 36 month period.

APPLICABILITY OF PRESUMPTION OF RELIANCE:

Fraud-on-the-Market Doctrine

121. At all relevant times, the market for Aeterna common stock was an efficient market for the following reasons, among others:

(a) Aeterna's stock met the requirements for listing, and is listed and actively traded on the NASDAQ, an highly efficient and automated market;

(b) During the class period, on average, over several hundreds of thousands of shares of Aeterna stock were traded on a weekly basis, demonstrating a very active and broad market for Aeterna stock and permitting a *very strong* presumption of an efficient market;

(c) As a regulated issuer, Aeterna filed periodic public reports with the SEC and was covered by multiple analysts;

(d) Aeterna regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(e) More than twenty NASDAQ member firms were active market-makers in Aeterna stock at all times during the Class Period; and

(f) Unexpected material news about Aeterna was rapidly reflected and incorporated into the Company's stock price during the Class Period.

122. As a result of the foregoing, the market for Aeterna common stock promptly digested current information regarding Aeterna from all publicly available sources and reflected such information in Aeterna's stock price. Under these circumstances, all purchasers of Aeterna common stock during the Class Period suffered similar injury through their purchase of Aeterna common stock at artificially inflated prices, and a presumption of reliance applies.

Affiliated Ute

123. Neither Plaintiffs nor the Class need prove reliance – either individually or as a class because under the circumstances of this case, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

124. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased the common stock of Aeterna during the Class Period and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

125. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aeterna's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate

discovery, Plaintiffs believe that there are at least hundreds of members in the proposed Class. Members of the Class may be identified from records maintained by Aeterna or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

126. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

127. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

128. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Aeterna;

(c) whether the Individual Defendants caused Aeterna to issue false and misleading statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) to what extent the members of the Class have sustained damages and the proper measure of damages.

129. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) Of The Exchange Act Against and Rule 10b-5 Promulgated Thereunder Against Aeterna, Engel, Blake, and Pelliccione

130. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

131. This claim is brought against Aeterna, Engel, Blake, and Pelliccione (the "Primary Defendants").

132. During the Class Period, the Primary Defendants carried out a plan, scheme and course of conduct that was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other members of the Class to purchase Aeterna common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Primary Defendants, and each of them, took the actions set forth herein.

133. Primary Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Aeterna common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. All Primary Defendants are sued as primary participants in the wrongful and illegal conduct charged herein and also as controlling persons as alleged below.

134. The Primary Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Aeterna as specified herein.

135. These Primary Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Aeterna's value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Aeterna and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Aeterna common stock during the Class Period.

136. Each of the Primary Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Primary Defendants were high-level executives, directors, and/or agents of the Company during the Class

Period and members of the Company's management team or had control thereof; (2) each of these defendants, by virtue of his or her responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's financial condition; (3) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's business and operations at all relevant times; and (4) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

137. The Primary Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Primary Defendants' material misrepresentations and/or omissions were done knowingly or recklessly.

138. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Aeterna common stock was artificially inflated during the Class Period. In

ignorance of the fact that market prices of Aeterna's publicly-traded common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Primary Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclose in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Aeterna common stock during the Class Period at artificially high prices and were or will be damaged thereby.

139. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding Aeterna's business operations and future prospects, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Aeterna common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices that they paid.

140. By virtue of the foregoing, Primary Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

141. As a direct and proximate result of Primary Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

142. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

COUNT II
Violation of Section 20(a) Of The Exchange Act
Against the Individual Defendants

143. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

144. By virtue of their high-level positions, agency, and their ownership and contractual rights, participation in and/or awareness and/or intimate knowledge of the misleading statements disseminated to the investing public, the Individual Defendants (Dodd, Blake, Pelliccione and Engel) had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the primary violator, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. In particular, each Individual Defendant had the power to control or influence the particular

transactions and statements giving rise to the securities violations as alleged herein, and exercised the same.

145. As set forth above, Aeterna violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint.

146. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

147. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

148. Determining that this action is a proper class action, certifying Plaintiffs as class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Class Counsel;

149. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be

proven at trial, including interest thereon;

150. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

151. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

October 14, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of October 2015 a true and correct copy of the foregoing document was served by CM/ECF to the parties registered to the Court's CM/ECF system.

/s/ Laurence Rosen